INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/811,130			
Filing Date	03/26/2004			
First Named Inventor	Prasad DEVARAJAN et al.			
Art Unit	1641			
Examiner Name	Christine E. FOSTER			
Attorney Docket Number	CHM-015			

	U.S. PATENT DOCUMENTS					
Examiner	Cite	Cito Document Nun	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant
Initials*	No.1	N	umber - Kind Code ² (if known)	MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear
		US-	4,302,471	11-24-1981	Casagrande et al	
		US	5,750,345	05-12-1998	Bowie	
		US-	6,114,123	09-05-2000	Murry et al	
		US-	6,143,720	11-07-2000	Conklin	
		US-	6,309,888	10-30-2001	Holvoet et al	
		US-	6,537,802	03-25-2003	Alocilja et al	
		US-	6,762,032	07-13-2004	Nelson et al	
		US-	2004/0121343	06-24-2004	Buechler et al	
		US-	2004/0132984	07-08-2004	Dieckmann et al	
		US-	2004/0203083	10-14-2004	Buechler et al	

	FOREIGN PATENT DOCUMENTS					
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines,	
Initials*	No.1	Country Code3-Number4-Kind Code5 (if known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T 6
		WO 2003/029462 A1	04-10-2003	Pieris Proteolab AG		

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T²
		ALLEN et al., Identification of a human neutrophil protein of M _r 24,000 that binds N-formyl peptides: co-sedimentation with specific granules, Biochimica et Biophysica Acta, 1989, Vol. 991, pp. 123-133.	
		AULITZKY et al., Measurement of Urinary Clusterin as an Index of Nephrotoxicity, Proc Soc Exp Biol Med 1992, Vol. 199, pp. 93-96.	Abst.
		BARTSCH et al., Cloning and Expression of human neutrophil lipocalin cDNA derived from bone marrow and ovarian cancer cells, FEBS Letters 357, 1995, pp. 255-259.	
		BELLOMO, R, ct al., Acute renal failure—definition, outcome measures, animal models, fluid therapy and information technology needs: the Second International Consensus Conference of the Acute Dialysis Quality Initiative (ADQI) Group, Acute Dialysis Quality Initiative Workgroup. Crit Care, Vol. 8, published May 24, 2004; pp. R204-212.	
		BOLIGNANO et al., Neutrophil gelatinase-associated lipocalin in patients with autosomal-dominant polycystic kidney deisease, Am J Nephrol, published online June 13, 2007, Vol. 27, pp. 373-378.	
		BOLIGNANO, D., Urinary neutrophil gelatinase-associated lipocalin (NGAL) is associated with severity of renal diaease in proteinuric patients, Nephrol Dial Transplant, 2007(e-published September 24, 2007), pp. 1-2.	

Examiner	Date	
Signature	Considered	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Comp	olete if Known
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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	Ι
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		BONVENTRE, J V, et al., Recent advances in the pathophysiology of ischemic acute renal failure, J Am Soc Nephrol, Vol. 14, Issue 8, August 2003, pp. 2199-2210.	
		BONVENTRE, J V, et al., Ischemic acute renal failure: An inflammatory disease?, Forefronts in Nephrology, Kidney International, August 2004, Vol. 66, Issue 2, pp. 480-485.	
		BRAUNWALD, E. ET AL., Harrison's Manual of Medicine, McGraw-Hill Company, January 31, 2002, pp. 653 and 656-658.	
		CHERTOW, G M, et al., Acute kidney injury, mortality, length of stay, and costs in hospitalized patients, J Am Soc Nephrol, Vol. 16, Issue 11, November 2005, pp. 3365-3370.	
		COSTANTINI et al., Pilot study on lipocalin expression into extracellular fluids of women in fertile age, Minerva Ginecologica, October 2002, Vol. 54, No. 5, pp. 387-392. (1 page)	Abst.
		COWLAND et al., Molecular Characterization and Pattern of Tissue Expression of the Gene for Neutrophil Gelatinase-Associated Lipocalin for Humans, Genomics, 1997, Vol. 45, pp. 17-23.	
		DENT, C L, et al., Plasma neutrophil gelatinase-associated lipocalin predicts acute kidney injury, morbidity and mortality after pediatric cardiac surgery: a prospective uncontrolled cohort study, BioMed Central Ltd, December 2007, http://ccforum.com/content/11/6/R127, (8 pages).	
		Devarajan Poster NGAL, DEVARAJAN et al, A Novel Biomarker of Renal Injury Following Cardiac Surgery, abstract of presentation at meeting of American Society of Nephrology, October 30, 2004. (1 page)	
		DEVARAJAN, P, et al., Gene Expression in Early Ischemic Renal Injury: Clues Toward Pathogenesis, Biomarker Discovery, and Novel Therapeutics, Molecular Genetics and Metabolism, Vol. 80, Issue 4, December 2003, pp. 365-376.	
		DEVARAJAN et al., http://www.aacc.org/NR/rdonlyres/17EFD95F-44C4-4920-AEFE-098E6FF A7295/0/DevarajanChristensonAACCslides.pdf, online December 14, 2006, pp. 1-45.	
		DEVIREDDY et al., Induction of Apoptosis by a Secreted Lipocalin That is Transcriptionally Regulated by IL-3 Deprivation, Science, August 3, 2001, Vol. 293, pp. 829-834.	
		DU CHEYRON et al., Urinary measurement of Na+/H+ exganger isoform 3 (NHE3) protein as new marker of tubule injury in critically ill patients with ARF, Am Kidney Dis, September 2003, Vol. 42, pp. 497-506.	
		FRIEDL et al., Neutrophil gelatinase-associated lipocalin in normal and neoplastic human tissue. Cell type-specific pattern of expression, The Histochemical Journal, 1999, Vol. 31, pp. 433-441.	
		GOTTLIEB, S S, et al., The prognostic importance of different definitions of worsening renal function in congestive heart failure, Journal of Cardiac Failure, Vol. 8, No. 3, June 2002, pp. 136-141.	
		HAN, W K, et al., Urinary biomarkers in the early diagnosis of acute kidney injury, Kidney International, http://kidney.international.org , online December 5, 2007, pp. 1-7.	
		HARD, G, Mechanisms of Chemically Induced Renal Carcinogenesis in the Laboratory Rodent, Toxicologic Pathology, 1998, Vol. 26, No. 1, pp. 104-112.	
		HARLOW et al, Antibodies: A Laboratory Manual, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY, 1988, pp. 340, 559, 578-581, and 591-593.	
		HERGET-ROSENTHAL, S, et al., Early detection of acute renal failure by serum cystatin C, Kidney International, Vol. 66, Issue 3, September 2004, pp. 1115-1122.	
		HERGET-ROSENTHAL, S, et al., Prognostic value of tubular proteinuria and enzymuria in nonoliguric acute tubular necrosis, Clin Chem, January 5, 2004, SO, pp 552-558.	

- 1	F	Data	
- 1	Examiner	Date	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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		HERGET-ROSENTHAL, S., One step forward in the early detection of acute renal failure, The Lancet, April 2, 2005, Vol. 365, pp. 1205-1206.	
		HIRSCH, R, et al., NGAL is an early predictive biomarker of contrast-induced nephropathy in children, Pediatr Nephrol, December 2007, Vol. 22, No. 12 (7 pages). e-published September 14, 2007	
		HORWITZ, L D, et al., Lipophilic siderophores of Mycobacterium tuberculosis prevent cardiac reperfusion injury, Proc. Natl. Acad. Sci. USA, April 1998, Vol. 95, pp. 5263-5268.	
		JONSSON et al., Extracorporeal circulation causes release of neutrophil gelatinase associated lipocalin (NGAL), Mediators of Inflammation, 1999, Vol. 8, pp. 169-171.	
		KJELDSEN et al., Isolation and Characterization of Gelatinase Granules From Human Neutrophils, Blood, March 15, 1994, Vol. 83, No. 6, pp. 1640-1649.	
		KJELDSEN et al., Structural and Functional Heterogeneity Among Peroxidase-Negative Granules in Human Neutrophils: Identification of a Distinct Gelatinase-Containing Granule Subset by Combined Immunocytochemistry and Subcellular Fractionation, Blood, November 15, 1993, Vol. 82, No. 10, pp. 3183-3191.	
		KJELDSEN et al., Identification of Neutrophil Gelatinase-Associated Lipocalin as a Novel Matrix Protein of Specific Granules in Human Neutrophils, Blood, February 1, 1994, Vol. 83, No. 3, pp. 799-807.	
		KOTANKO et al., Urinary N-Acetyl-Beta-D-Glucosaminidase and Neopterin Aid in the Diagnosis of Rejection and Acute Tubular Necrosis in Intially Nonfuntioning Kidney Grafts, Nephron, 2000, Vol. 84, pp. 228-335. KUBES, P et al, Therapeutic potential of inhibiting leukocyte rolling in ischemia/reperfusion, J Clin	
		Invest, June 1995, Vol. 95, Issue 6, pp. 2510-2519.	
		Kunis Poster NGAL, KUNIS et al, Ngal (Neutrophil Gelatinase-Associated Lipocalin) as a Marker for Tubular Damage in Patients with Acute Tubular Necrosis (ATN), abstract of presentation at meeting of American Society of Nephrology, October 31, 2004. (1 page)	
		KWON et al., Urinary actin, interleukin-6, and interleukin-8 may predict sustained ARF after ischemic injury in renal allografts, Am Kidney Dis, May 2003, Vol. 41, pp. 1074-1087.	
		LAMEIRE, N, et al., Reflections on the definition, classification, and diagnostic evaluation of acute renal failure [Editorial], Current Opinion in Critical Care, Vol. 10, December 2004, pp. 468-475.	
		LASSNIGG, A, et al., Minimal changes of serum creatinine predict prognosis in patients after cardiothoracic surgery: a prospective cohort study, J Am Soc Nephrol, Vol. 15, Issue 6, June 2004, pp. 1597-1605.	
		LIU et al., Identification of a New Acute Phase Protein, J Biol Chem, 1995, Vol. 270, pp. 22565-22570.	
		MORI, J, et al., Endocytic delivery of lipocalin-siderophore-iron complex rescues the kidney from ischemia-reperfusion injury, The Journal of Clinical Investigation, Vol. 115, No. 3, March 2005, pp.610-621.	
		NIELSEN et al., Rectal dialysate and fecal concentrations of neutrophil gelatinase-associated lipocalin, interleukin-8, and tumor necrosis factor [alpha] in ulcerative colitis, The American Journal of Gastroenterology, October 1, 1999, Vol. 94(10), pp. 2923-2928.	
		NICKOLAS, T, et al., A Single Measurement of Urine Neutrophil Gelatinase-Associated Lipocalin Indentifies Acute Kidney Injury at Hospital Presentation and Predicts Poor Outcome, Clinical Nephrology: Acute Kidney Injury: Clinical II, Poster Board No. SU-PO953, November 4, 2007 (1 page).	
		PARIKH et al., Urine NGAL and IL-18 are Predictive Biomarkers for Delayed Graft Function Following Kidney Transplantation, American Journal of Transplantation, May 8, 2009, Vol. 6, pp. 1639-1645.	
		PARIKH et al., Urinary interleukin 18 is a marker of human acute tubular necrosis, Am Kidney Dis, March 2004, Vol. 43, Issue 3, pp. 405-414.	
xamine ignature		Date Considered	

Complete if Known INFORMATION DISCLOSURE Application Number 10/811,130 Filing Date 03/26/2004 STATEMENT BY APPLICANT First Named Inventor Prasad DEVARAJAN et al. (use as many sheets as necessary) Art Unit Examiner Name Christine E. FOSTER 4 Sheet 4 of Attorney Docket Number CHM-015

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, include name of the author (in CAPITAL LETTERS)), title of the article (when appropriate), title of the item (book, magazine, include name of the author (in CAPITAL LETTERS)).	
Initials*	No.1	journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T ²
		PENDERS et al., Alpha 1-microglobulin: clinical laboratory aspects and applications, Clinica Chimica Acta, August 16, 2004, Vol. 346, Issue 2, pp. 107-118. (on-line June 17, 2004)	
		RABB H., Novel Urinary markers for early diagnosis of ARF, Am Kidney Dis., September 2003, Vol. 42, Issue 3, pp 599-600.	
		SINGBARTL, K et al, Blocking P-selectin protects from ischemia/reperfusion induced acute renal failure, FASEB J 14; 2000, pp. 48-54.	
		SMITH, G L, et al., Worsening Renal Function: What Is a Clinically Meaningful Change in Creatinine During Hospitalization With Heart Failure?, Journal of Cardiac Failure, Vol. 9, No. 1, February 2003, pp. 13-25.	
		SCHMIDT-OTT, K M, et al., Duel Action of Neutrophil Gelatinase-Associated Lipocalin, J Am Soc Nephrol, Vol. 18, Issue 2, February 2007, pp 407-413.	
		STAR, R A, Treatment of acute renal failure, Kidney International, Vol. 54, 1998, pp. 1817-1831.	
		STOESZ et al., Overexpression of neu-related lipocalin (NRL) in neu-initiated but not ras or chemically initiated rat mammary carcinomas, Oncogene, December 7, 1995, Vol. 11, Issue 11, pp. 2233-2241.	Abst.
		TRIEBEL et al., A 25 kDa alpha2-microglobulin-related protein is a component of the 125 kDa form of human gelatinase, FEBS, December 21, 1992, Vol. 314(3), pp. 386-388.	
		TSUCHIDA et al., Lipocalin-Type Prostaglandin D Synthase in Urine in Adriamycin-Induced Nephropathy of Mice, Nephron Physiol, February 2004, Vol. 96, pp. 42-51.	
		TUTTLE et al., Predictors of ARF after cardiac surgical procedures. AM J Kidney Dis., January 2003, Vol. 41, Issue 1, (12 pages).	
		VENGE, P., Soluble markers of allergic inflammation, Allergy, 1994, Vol. 49, pp. 1-8.	
		WU et al, Analytical and clinical evaluation of new diagnostic tests for myocardial damage, Clinica Chimica Acta 272 (1998) 11-21.	
		XU et al., Serum measurements of human neutrophil lipocalin (HNL) discriminates between acute bacterial and viral infections, Scand J Clin Lab Invest, 1995, Vol. 55, pp. 125-131.	
		YANG, J., et al, Iron, lipocalin and kidney epithelia, Am.J.Physiol Renal Physiol, Vol. 285, Issue 1, July 2003, pp. F9-F18.	
		ZEREGA et al., Expression of NRL/NGAL (neu-related lipocalin/neutrophil gelatinase-associated lipocalin) during mammalian embryonic development and in inflammation, European Journal of Cell Biology, March 2000, Vol. 79, No. 3, pp. 165-172. (1 page)	Abst.

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Signature	Considered	